

**REMARKS**

The Non-Final Office Action dated June 24, 2003 has been carefully reviewed and the following remarks are made in response thereto. In view of these remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

By this Amendment, claims 27-34, 68-75 and 77-82 have been newly canceled and claims 83-87 have been newly added. As a result of this amendment, claims 83-87 are currently before the Examiner. The newly-added method claims are directed to subject matter that falls within the elected Group II (*i.e.*, a method of evaluating an herbal composition). See, for example, previously-elected claims 69-75.

Support for the newly presented claims can be found throughout the as-filed specification and in the previously-pending claims. For example, support for the phrase “quality control method” can be found *inter alia* in the “Field of the Invention” at page 1, line 6 (“methodologies for improving...quality control...of herbal compositions”); in Example 5 at pages 43-44 (“Quality Control”); and in Example 8 at pages 50, lines 17-18 (“[t]he quality of a test batch will be determined by comparing test HRB and standard ginseng Standardized HBR Array variables...”); as well as throughout Examples 9-11 at pages 50-56.

Support for the phrase “multiple chemical components” can be found *inter alia* at page 2, lines 11-13) (“each formula of TCM typically contains hundreds of chemical entities from several herbs”); at page 7, lines 19-21 (“[t]he multitude of relevant biological responses induced by the multiple chemicals in herbs...”); and at page 13, lines 24-27 (“in biological systems that are treated or challenged with multiple chemicals at the same time, such as herbal medicines and TCM”).

Support for the phrase “whole plants or plant parts” can be found *inter alia* in the definition of “Herbs” at page 20, line 5 (“any...plant or plant part”) and in the definition of “Herbal Composition” at page 20, line 15-16 (“a whole plant or a plant part”).

Support for the phrase “gene expression profiles” can be found *inter alia* at page 40, line 28 (“gene expression profiles for marker data”) and at pages 65-69, including the gene expression profile data provided in Table 10.

Support for the phrase "quantitative similarity value" is supported by the disclosure on statistics found *inter alia* at page 40, lines 20-28; at page 48, lines 25-28 to page 49, lines 1-10; and at page 50, lines 14-26.

Applicants assert that no new matter has been introduced as a result of these claim amendments.

### **Statement of the Substance of the Examiner Interview**

As required by M.P.E.P. § 713.04, Applicants hereby provide a statement of the substance of the Examiner Interview conducted on October 21, 2003. As set forth in the Interview Summary on Form PTOL-413, the following people attended the interview: Erich E. Veitenheimer, Ph.D. (Applicants' representative); Robert Tilton, Ph.D. (Vice President of Science and Technology for PhytoCeutica, Inc.); Ardin Marschel (Primary Patent Examiner) and C. Dune Ly (Patent Examiner). Applicants thank Examiner Ly and Primary Examiner Marschel for conducting the interview.

First, Dr. Tilton gave a brief overview of the work at Yale University and PhytoCeutica that led to the discovery of the invention. He explained that the lack of quality control in the preparation and administration of herbal compositions has led to a lack of uniformity in the industry, sometimes leading to personal injury for people taking such compositions. Next, the participants reviewed the pending claims and the outstanding rejections, particularly the 102(b) rejection over Schena *et al.* (1996). The Examiners indicated that they believed the pending claims did not clearly distinguish the invention over the prior art of record. The Examiners and Applicants discussed possible claim amendments that would more clearly distinguish the presently claimed invention over the prior art of record. Applicants believe that newly presented independent claim 83 captures the claim language which they believe should satisfy the Examiners' concerns as stated at the interview.

### **Objections**

The Office Action objected to claims 32-34 and 75 as being directed to non-elected subject matter. The Examiner is respectfully requested to withdraw the objection in light of the

cancellation of these claims. All of the presently-pending claims are directed to subject matter of the elected group.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 28 and 30-33 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Office Action states that the abbreviation “HBR” as used in claim 28 is vague and indefinite unless accompanied by the full name. Claims 30-33 are included in the rejection since they depend from claim 28.

Applicants have newly canceled claims 28 and 30-33 without prejudice. Newly presented independent claim 83 (the only pending independent claim) includes the following phrase: “Herbal BioResponse (HBR).” In view of these amendments, the Examiner is respectfully requested to withdraw the rejection.

### **Rejections under 35 U.S.C. § 102(b)**

Claims 27-34, 68, 69 and 70-75 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Schena et al. (1996). All of the rejected claims have been newly canceled, so this rejection will now be discussed in the context of newly added claims 83-87.

Schena *et al.* teach using microarrays to examine the physiological response of cultured human T (Jurkat) cells under control, heat-treated and phorbol ester treatment. Thus, Schena *et al.* disclose comparing the cellular effects of a single chemical (i.e., phorbol ester) to a control cell. According to the authors, the purpose of the study is to demonstrate that “parallel gene analysis with microarrays provides a rapid and efficient method for large-scale human gene discovery” (Abstract).

In contrast to the teaching of Schena *et al.*, the claims of the present application are directed to a method of quality control for assessing the equivalency of a test batch of an herbal composition to a standardized batch of the same or substantially same herbal composition, wherein the herbal composition comprises multiple chemical components derived from one or more whole plants or plant parts. Since Schena *et al.* fail to disclose any method of quality

control involving herbal compositions, yet alone a method which involves testing multiple chemical components derived from a whole plant or a plant part, they fail to anticipate the instantly claimed invention. Furthermore, the cited reference fails to provide any teaching or motivation that would render the claimed quality control method obvious.

For the above reasons, the teachings of Schena *et al.* fail to anticipate or render obvious the claimed method of quality control. For these reasons, the Examiner is respectfully requested to withdraw the rejection.

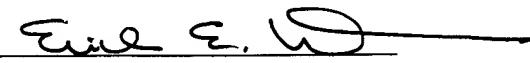
### Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: November 24, 2003  
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